

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GENUS LIFESCIENCES INC.,

Plaintiff,

v.

LANNETT COMPANY, INC.,

Defendant.

C.A. No. _____

JURY TRIAL DEMANDED

COMPLAINT

Genus Lifesciences Inc. (“Genus” or “Plaintiff”), by its undersigned attorneys, for its Complaint against defendant Lannett Company, Inc. (“Lannett”), alleges as follows:

PRELIMINARY STATEMENT

1. This is an action for patent infringement of U.S. Patent Nos. 9,867,815; 10,016,407; and 10,420,760 (collectively, “the Patents-in-Suit”) under the patent laws of the United States, Title 35, United States Code § 100, *et seq.* This action relates to Lannett’s commercial manufacture, use, sale, and offer for sale of cocaine hydrochloride pharmaceutical products before the expiration of the Patents-in-Suit.

2. Genus is a specialty pharmaceutical company engaged in the development and commercialization of generic and branded pharmaceutical products. Genus holds approved New Drug Application (“NDA”) No. 209963 for GOPRELTO (cocaine hydrochloride nasal solution, 4%). Medical professionals use GOPRELTO for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults. GOPRELTO is the first ever FDA-approved drug product containing cocaine

hydrochloride in the United States. The U.S. Federal Food & Drug Administration (“FDA”) approved GOPRELTO in December 2017, and it is now available throughout the United States.

3. GOPRELTO and the use of GOPRELTO is covered by one or more claims of the Patents-in-Suit.

4. Upon information and belief, Lannett is in the business of, among other things, manufacturing and selling pharmaceutical products for the U.S. market. Lannett is marketing a similar cocaine hydrochloride drug product to Genus’s GOPRELTO under the name NUMBRINO.

THE PARTIES, JURISDICTION, AND VENUE

5. Genus is a Pennsylvania corporation organized under the laws of the State of Pennsylvania, with a principal place of business at 514 North 12th Street, Allentown, Pennsylvania 18102.

6. Lannett is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9000 State Road, Philadelphia, Pennsylvania 19136.

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338 because this is a patent infringement action that arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because Lannett is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

9. This Court has personal jurisdiction over Lannett because, among other things, Lannett purposefully availed itself of the benefits and protections of Delaware’s laws such that it should reasonably anticipate being haled into court here. Lannett is a corporation organized and

existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, Lannett's drug product NUMBRINO is used and administered within and throughout the United States, including in Delaware. On information and belief, NUMBRINO is administered by medical professionals practicing in Delaware. Each of these activities has a substantial effect within Delaware, as they constitute indirect infringement of the Patents-in-Suit.

10. Additionally, Lannett sells other pharmaceutical products throughout the United States, including Delaware. Upon information and belief, Lannett derives substantial revenue from its Delaware drug sales.

11. Upon information and belief, Lannett has previously availed itself of this forum for the purpose of litigating business disputes. For example, in *Impax Laboratories, Inc. et al. v. Lannett Holdings, Inc. and Lannett Company, Inc.*, No. 1:14-cv-00999-RGA (D. Del.), Lannett consented to personal jurisdiction in this District. By way of another example, in *Lannett Company, Inc. v. KV Pharmaceuticals et al.*, No. 1:08-cv-00338-JJF (D. Del.), Lannett selected this District to file suit.

THE PATENTS-IN-SUIT

12. United States Patent No. 9,867,815 (the "'815 patent"), titled "Pharmaceutical Compositions and Methods of Using the Same," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on January 16, 2018, to Genus, the assignee of the named inventors. Genus has been, and continues to be, the sole assignee and owner of the '815 patent.

13. A true and correct copy of the '815 patent is attached as Exhibit A.

14. The '815 patent is generally directed to a method of administering cocaine hydrochloride by soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising about 3.6% to about 4.4% cocaine hydrochloride, about 0.07% to about 0.20% sodium benzoate, about 0.125% citric acid, and water, and contacting each pledget on a mucous membrane of a subject with hepatic or renal impairment, and/or patients over the age of 65, for about 20 minutes.

15. United States Patent No. 10,016,407 (the "'407 patent"), titled "Pharmaceutical Compositions and Methods of Using the Same," was duly and legally issued by the PTO on July 10, 2018, to Genus, the assignee of the named inventors. Genus has been, and continues to be, the sole assignee and owner of the '407 patent.

16. A true and correct copy of the '407 patent is attached as Exhibit B.

17. The '407 patent is generally directed to a method of administering cocaine hydrochloride by soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising about 3.6% to about 4.4% cocaine hydrochloride, about 0.07% to about 0.20% sodium benzoate, an acidulant, and water, and contacting each pledget on a nasal mucous membrane of a subject with hepatic or renal impairment for up to 20 minutes.

18. United States Patent No. 10,420,760 (the "'760 patent"), titled "Pharmaceutical Compositions and Methods of Using the Same," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on September 24, 2019, to Genus, the assignee of the named inventors. Genus has been, and continues to be, the sole assignee and owner of the '760 patent.

19. A true and correct copy of the '760 patent is attached as Exhibit C.

20. The '760 patent is generally directed to a method for induction of local anesthesia prior to performing a procedure on, through, or adjacent to a mucous membrane of the nasal

cavities of a patient by administering a specific composition of cocaine hydrochloride solution to a patient if the estimated glomerular filtration rate ranges from about 15 mL/min./1.73 m² to less than about 60 mL/min./1.73 m².

LANNETT'S INFRINGEMENT OF THE PATENTS-IN-SUIT

21. Lannett commercially manufactures, sells, and offers for sale NUMBRINO (cocaine hydrochloride) nasal solution, 4% (40 mg/mL) in the United States. Lannett's wholly owned subsidiary, Cody Laboratories, Inc. ("Cody Labs"), holds NDA No. 209575 for NUMBRINO, which was approved by the FDA on January 10, 2020.

22. Upon information and belief, Lannett controls or otherwise directs and authorizes the activities of Cody Labs, including with respect to NDA No. 209575. For example, Lannett has closed the Cody Labs facility, ceased all operations of Cody Labs, and has retained control of NDA No. 209575 for NUMBRINO. In addition, correspondence with the FDA related to NDA No. 209575 is directed to Lannett employees. Upon information and belief, Cody Labs and Lannett share a close connection and/or are acting as one company. Any acts of Cody Labs are attributable to Lannett because at all relevant times, Cody Labs was acting as Lannett's agent.

23. Lannett sells NUMBRINO with an insert containing Prescribing Information (the "NUMBRINO Label"), which details, among other things, the indication, dosing, and risks associated with NUMBRINO.

24. A true and correct copy of the NUMBRINO Label is attached as Exhibit D.

25. On information and belief, NUMBRINO is sold in a bottle containing 4% cocaine hydrochloride, purified water, 0.13% citric acid (anhydrous), 0.1% sodium benzoate, D&C Yellow No. 10 (a coloring additive), and FD&C Green No. 3 (a coloring additive). (*See* Exhibit D § 11 Description.) Although the NUMBRINO Label does not mention the amounts of citric acid and

sodium benzoate in the product, Cody Labs has a pending patent application titled, “Preparation of (-)-Cocaine Hydrochloride,” that describes the NUMBRINO cocaine formulation (used in Phase III clinical trials) as including 4% cocaine HCl, 0.1% sodium benzoate, and 0.133% citric acid. *See* U.S. Publication No. 2019/0224184 ¶ [286], Table 11. Upon information and belief, because NUMBRINO is an aqueous solution with a density of about 1 g/mL, the weight/volume % and the weight/weight % are similar.

26. The NUMBRINO Label instructs medical professionals to administer NUMBRINO by soaking one or more pledgets in about 4 mL of a ready-to-use solution composition, contacting each pledget on a nasal mucous membrane of the subject for about 20 minutes, and removing each pledget. (Exhibit D § 2.3 Preparation and Administration of NUMBRINO via Pledgets.)

27. The NUMBRINO Label instructs medical professionals to administer NUMBRINO prior to performing a nasal endoscopy on a patient. For example, the NUMBRINO Label states that NUMBRINO is indicated “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.* § 1 Indications and Usage.) A nasal endoscopy is a diagnostic procedure or surgery on or through the nasal cavity.

28. The NUMBRINO Label further instructs medical professionals to use NUMBRINO in patients with renal impairment, and to “follow a conservative approach,” and to monitor patients with renal impairment for adverse events. (*Id.* § 8.7 Renal Impairment.)

29. The NUMBRINO Label instructs and induces medical professionals to use NUMBRINO in patients over 65 years of age. (*Id.* § 8.5 Geriatric Use.)

COUNT I
(Infringement of the '815 Patent)

30. Genus re-alleges and incorporates by reference paragraphs 1 through 29 as if fully alleged herein.

31. Lannett has known of the '815 patent since at least May 16, 2018. On May 16, 2018, Lannett identified the '815 patent in an Information Disclosure Statement submitted during the prosecution of U.S. Patent Application No. 15/981,574, assigned to Lannett's wholly owned subsidiary Cody Labs.

32. Lannett infringes the '815 patent by making, using, offering to sell, or selling NUMBRINO in the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. §§ 271(a), (b), (c), and/or (g), literally and/or through the doctrine of equivalents.

33. Claim 10 of the '815 patent recites a method of administering a local anesthetic prior to performing a nasal endoscopy on a subject with hepatic or renal impairment comprising soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising: about 3.6% to about 4.4% cocaine hydrochloride; about 0.07% to about 0.20% sodium benzoate; about 0.125% citric acid; and optionally, at least one coloring additive; and water, contacting each pledget on a nasal mucous membrane of the subject for about 20 minutes, and removing each pledget.

34. Lannett induces the infringement of claim 10. The NUMBRINO Label instructs medical professionals to administer a local anesthesia prior to performing a nasal endoscopy on a subject with renal impairment. (Exhibit D §§ 1, 8.7.) The NUMBRINO Label further instructs medical professionals to administer NUMBRINO by soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising 4% cocaine hydrochloride (i.e., about 3.6% to about 4.4% cocaine hydrochloride), 0.1 % sodium benzoate (i.e., about 0.07% to about 0.20% sodium

benzoate); 0.13% citric acid (anhydrous) (i.e., about 0.125% citric acid), and water. (*See id.* §§ 2.3, 11.) The NUMBRINO Label further instructs medical professionals to apply 4 mL of NUMBRINO to four pledgets, place one or two pledgets in a nasal mucous membrane of the subject, leave the pledgets in place for up to 20 minutes, and remove the pledgets. (*Id.* § 2.3.)

35. Claim 20 of the '815 patent recites the method of claim 10, wherein the subject has renal impairment. Lannett induces the infringement of claim 20 because the NUMBRINO Label instructs medical professionals that they can administer NUMBRINO to patients with renal impairment, and to monitor such patients for adverse events. (*Id.* §§ 1, 8.7.)

36. Claim 26 of the '815 patent recites a method of administering a local anesthetic on a subject over the age of 65 and undergoing a diagnostic or surgical procedure, comprising: soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising: about 3.6% to about 4.4% cocaine hydrochloride; about 0.07% to about 0.20% sodium benzoate; about 0.125% citric acid; and optionally, at least one coloring additive; and water, contacting each pledget on a mucous membrane of the subject for about 20 minutes, and removing each pledget.

37. Lannett induces the infringement of claim 26. The NUMBRINO Label instructs medical professionals to administer a local anesthesia prior to performing a diagnostic or surgical procedure on geriatric subjects (i.e., age 65 and older). (*Id.* §§ 1, 8.5.) The NUMBRINO Label further instructs medical professionals to administer NUMBRINO by soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising 4% cocaine hydrochloride (i.e., about 3.6% to about 4.4% cocaine hydrochloride), 0.1% sodium benzoate (i.e., about 0.07% to about 0.20% sodium benzoate); 0.13 % citric acid (anhydrous) (i.e., about 0.125% citric acid), and water. (*See id.* §§ 2.3, 11.) The NUMBRINO Label further instructs medical professionals to

apply 4 mL of NUMBRINO to four pledgets, place one or two pledgets in a mucous membrane of the subject, leave the pledgets in place for up to 20 minutes, and remove the pledgets. (*Id.* § 2.3.)

38. Claim 27 of the '815 patent recites the method of claim 26 wherein the subject is over 70 years old. Lannett induces the infringement of claim 27 because the NUMBRINO Label instructs medical professionals that they can administer NUMBRINO to patients over 70 years old. (*Id.* §§ 1, 8.5.)

39. Claim 28 of the '815 patent is directed to the method of claim 26 wherein the subject is over 80 years old. Lannett induces the infringement of claim 28 because the NUMBRINO Label instructs medical professionals that they can administer NUMBRINO to patients over 70 years old, which includes patients 80 years old. (*Id.* §§ 1, 8.5.)

40. Lannett, acting without authority, consent, right, or license of the '815 patent, has induced, and continues to induce medical professionals to administer and use NUMBRINO which directly infringes one or more claims of the '815 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b). More specifically, medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 10, 20, and 26–28 of the '815 patent by using NUMBRINO, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

41. On information and belief, Lannett actively and knowingly causes third parties to infringe claims 10, 20, and 26–28 of the '815 patent with the specific intent to cause such infringement. Lannett possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, the NUMBRINO Label, which provides instructions on how to use NUMBRINO in a manner that infringes directly the '815 patent.

42. Lannett has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to use NUMBRINO by marketing, promoting and advertising the infringing use of NUMBRINO.

43. Lannett's foregoing actions constitute active inducement of infringement of the '815 patent.

44. Upon information and belief, Lannett has acted with full knowledge of the '815 patent and without a reasonable basis for believing that it would not be liable for active inducement of infringement of the '815 patent.

45. Genus has been damaged as a result of Lannett's infringing conduct.

46. Lannett is thus liable to Genus in an amount that adequately compensates for its infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

47. On information and belief, Lannett has willfully infringed the '815 patent. Genus is entitled to increased damages of three times the damages assessed pursuant to 35 U.S.C. § 284, as well as an award of attorney's fees pursuant to 35 U.S.C. § 285.

COUNT II
(Infringement of the '407 Patent)

48. Genus re-alleges and incorporates by reference paragraphs 1 through 47 as if fully alleged herein.

49. Lannett has known of the '407 patent at least as early as January 10, 2020, if not earlier.

50. Lannett infringes the '407 patent by making, using, offering to sell, or selling NUMBRINO in the United States, and by actively inducing and/or contributing to infringement

by others, in violation of 35 U.S.C. §§ 271(a), (b), (c), and/or (g), literally and/or through the doctrine of equivalents.

51. Claim 1 of the '407 patent recites a method of administering a local anesthetic prior to performing a diagnostic or surgical procedure on a subject with hepatic or renal impairment comprising: soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising: soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising: about 3.6% to about 4.4% cocaine hydrochloride; about 0.07% to about 0.20% sodium benzoate; an acidulant; optionally, at least one coloring additive; and water, contacting each pledget on a nasal mucous membrane of the subject for up to 20 minutes, and removing each pledget.

52. Lannett induces the infringement of claim 1. The NUMBRINO Label instructs medical professionals to administer a local anesthesia prior to performing a diagnostic or surgical procedure on a subject with renal impairment. (Exhibit D §§ 1, 8.7.) The NUMBRINO Label further instructs medical professionals to administer NUMBRINO by soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising 4% cocaine hydrochloride (i.e., about 3.6% to about 4.4% cocaine hydrochloride), 0.1% sodium benzoate (i.e., about 0.07% to about 0.20% sodium benzoate); citric acid (anhydrous) (i.e., an acidulant), D&C Yellow No. 10 (a coloring additive), and FD&C Green No. 3 (a coloring additive), and water. (*See id.* §§ 2.3, 11.) The NUMBRINO Label further instructs medical professionals to apply 4 mL of NUMBRINO to four pledgets, contacting each pledget on a nasal mucous membrane of a subject for up to 20 minutes, and removing each pledget. (*Id.* § 2.3.)

53. Claim 6 recites the method of claim 1, wherein the subject has renal impairment. Lannett induces infringement of claim 6 because the NUMBRINO Label instructs medical

professionals that they can administer NUMBRINO to patients with renal impairment and to monitor such patients for adverse events. (*Id.* §§ 1, 8.7.)

54. Claim 9 recites the method of claim 1, wherein the procedure is a nasal endoscopy. Lannett induces infringement of claim 9 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.* § 1.) A nasal endoscopy is a type of diagnostic procedure on or through the nasal cavities in adults.

55. Claim 10 recites a method of claim 1, wherein the acidulant is citric acid. Lannett induces infringement of claim 10 because NUMBRINO contains citric acid as an acidulant. (*Id.* § 11.)

56. Claim 11 recites a method of administering a local anesthetic prior to performing a diagnostic or surgical procedure on a subject with hepatic or renal impairment comprising: soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising: about 3.6% to about 4.4% cocaine hydrochloride; a preservative, about 0.01% to about 1.0% citric acid; optionally, at least one coloring additive; and water, contacting each pledget on a nasal mucous membrane of the subject for up to 20 minutes, and removing each pledget.

57. Lannett induces infringement of claim 11 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO as a local anesthetic prior to performing a diagnostic procedure on a subject with renal impairment. (*Id.* §§ 1, 8.7.) The NUMBRINO Label further instructs medical professionals to administer NUMBRINO by soaking one or more pledgets in about 4 mL of a ready-to-use composition comprising 4% cocaine hydrochloride (i.e., about 3.6% to about 4.4% cocaine hydrochloride), sodium benzoate (i.e., a preservative); 0.13%

citric acid (anhydrous) (i.e., about 0.01% to about 1.0% citric acid), D&C Yellow No. 10 (a coloring additive), and FD&C Green No. 3 (a coloring additive), and water. (*See id.* §§ 2.3, 11.) The NUMBRINO Label further instructs medical professionals to apply 4 mL of NUMBRINO to four pledgets, contacting each pledget on a nasal mucous membrane of a subject for up to 20 minutes, and removing each pledget. (*Id.* § 2.3.)

58. Claim 16 claims the method of claim 11, wherein the subject has renal impairment. Lannett induces infringement of claim 16 because the NUMBRINO Label instructs medical professionals that they can administer NUMBRINO to patients with renal impairment and to monitor such patients for adverse events. (*Id.* §§ 1, 8.7.)

59. Claim 19 claims the method of claim 11, wherein the procedure is a nasal endoscopy. Lannett induces infringement of claim 19 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.* § 1.) A nasal endoscopy is a type of diagnostic procedure on or through the nasal cavities in adults.

60. Claim 20 claims the method of claim 11, wherein the preservative is sodium benzoate. Lannett induces infringement of claim 20 because NUMBRINO contains sodium benzoate as a preservative. (*Id.* § 11.)

61. Lannett, acting without authority, consent, right, or license of the ’407 patent, has induced, and continues to induce medical professionals to administer and use NUMBRINO which directly infringes one or more claims of the ’407 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b). More specifically, medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1, 6, 9, 10, 11,

16, 19, and 20 of the '407 patent by using NUMBRINO, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

62. On information and belief, Lannett actively and knowingly causes third parties to infringe claims 1, 6, 9, 10, 11, 16, 19, and 20 of the '407 patent with the specific intent to cause such infringement. Lannett possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, the NUMBRINO Label, which provides instructions on how to use NUMBRINO in a manner that infringes directly the '407 patent.

63. Lannett has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to use NUMBRINO by marketing, promoting and advertising the infringing use of NUMBRINO.

64. Lannett's foregoing actions constitute active inducement of infringement of the '407 patent.

65. Upon information and belief, Lannett has acted with full knowledge of the '407 patent and without a reasonable basis for believing that it would not be liable for active inducement of infringement of the '407 patent.

66. Genus has been damaged as a result of Lannett's infringing conduct.

67. Lannett is thus liable to Genus in an amount that adequately compensates for its infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

68. On information and belief, Lannett has willfully infringed the '407 patent. Genus is entitled to increased damages of three times the damages assessed pursuant to 35 U.S.C. § 284, as well as an award of attorney's fees pursuant to 35 U.S.C. § 285.

COUNT III
(Infringement of the '760 Patent)

69. Genus re-alleges and incorporates by reference paragraphs 1 through 68 as if fully alleged herein.

70. Lannett has known of the '760 patent at least as early as January 10, 2020, if not earlier.

71. Lannett infringes the '760 patent by making, using, offering to sell, or selling NUMBRINO in the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. §§ 271(a), (b), (c), and/or (g), literally and/or through the doctrine of equivalents.

72. Claim 1 of the '760 patent recites a method for induction of local anesthesia prior to performing a diagnostic procedure on, through, or adjacent to a mucous membrane of the nasal cavities of a patient comprising: determining an estimated glomerular filtration rate for a patient; soaking a plurality of absorbent articles in an aqueous solution comprising sodium benzoate, citric acid, and about 4% cocaine hydrochloride, by weight; and contacting at least one of the plurality of absorbent articles with a mucous membrane of the patient for up to about 20 minutes to reduce sensation in a body region of the patient if the estimated glomerular filtration rate ranges from about 15 mL/min./1.73 m² to less than about 60 mL/min./1.73 m².

73. Lannett induces infringement of claim 1 because the NUMBRINO Label instructs medical professionals to use NUMBRINO for the induction of local anesthesia prior to performing a diagnostic procedure on, through, or adjacent to a mucous membrane of the nasal cavities of a patient. (Exhibit D § 1.) The NUMBRINO Label further instructs medical professionals to undertake a “conservative approach” when administering NUMBRINO to patients with renal impairment, which requires the physician to determine whether the patient has renal impairment

before administering it. (*Id.* § 8.7.) Determining an estimated glomerular filtration rate for a patient is a method for determining renal impairment. The NUMBRINO Label further instructs medical professionals to administer NUMBRINO by soaking a plurality of absorbent articles in NUMBRINO which is an aqueous solution comprising sodium benzoate, citric acid, and about 4% cocaine hydrochloride, by weight; contacting at least one of the plurality of absorbent articles with a mucous membrane of the patient for up to about 20 minutes to reduce sensation in a body region of the patient. (*Id.* §§ 2.3, 11.) The NUMBRINO Label further instructs medical professionals to use NUMBRINO in patients with renal impairment. (*Id.* § 8.7.) Individuals with renal impairment have estimated glomerular filtration rate ranges from about 15 mL/min./1.73 m² to less than about 60 mL/min./1.73 m².

74. Claim 4 recites the method of claim 1, wherein the aqueous solution further comprises at least one coloring additive. Lannett induces infringement of claim 4 because NUMBRINO includes D&C Yellow No. 10 (a coloring additive) and FD&C Green No. 3 (a coloring additive). (*Id.* § 11.)

75. Claim 7 recites the method of claim 1, wherein the diagnostic procedure comprises nasal endoscopy. Lannett induces infringement of claim 7 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.* § 1.) A nasal endoscopy is a type of diagnostic procedure on or through the nasal cavities in adults.

76. Claim 8 recites the method of claim 1, wherein the diagnostic procedure comprises laryngoscopy. Lannett induces infringement of claim 8 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the

mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.*) A laryngoscopy is a type of diagnostic procedure on or through the nasal cavities in adults.

77. Claim 9 recites the method of claim 1, wherein the diagnostic procedure comprises nasopharyngeal laryngoscopy. Lannett induces infringement of claim 9 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.*) A nasopharyngeal laryngoscopy is a type of diagnostic procedure on or through the nasal cavities in adults.

78. Claim 10 claims the method of claim 1, wherein the diagnostic procedure comprises transnasal esophagoscopy. Lannett induces infringement of claim 11 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.*) A transnasal esophagoscopy is a type of diagnostic procedure on or through the nasal cavities in adults.

79. Claim 11 claims the method of claim 1, wherein the diagnostic procedure comprises nasal stroboscopy. Lannett induces infringement of claim 11 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.*) A nasal stroboscopy is a type of diagnostic procedure on or through the nasal cavities in adults.

80. Claim 12 of the ’760 patent recites a method for induction of local anesthesia prior to performing a medical procedure on, through, or adjacent to a mucous membrane of the nasal

cavities of a patient comprising: determining an estimated glomerular filtration rate for a patient; soaking a plurality of absorbent articles in an aqueous solution comprising sodium benzoate, citric acid, and about 4% cocaine hydrochloride, by weight; and contacting at least one of the plurality of absorbent articles with a mucous membrane of the patient for up to about 20 minutes to reduce sensation in a body region of the patient if the estimated glomerular filtration rate ranges from about 15 mL/min./1.73 m² to less than about 60 mL/min./1.73 m².

81. Lannett induces infringement of claim 12 because the NUMBRINO Label instructs medical professionals to use NUMBRINO for the induction of local anesthesia prior to performing a medical procedure on, through, or adjacent to a mucous membrane of the nasal cavities of a patient. (*Id.*) The NUMBRINO Label further instructs medical professionals to undertake a “conservative approach” when administering NUMBRINO to patients with renal impairment, which requires the physician to determine whether the patient has renal impairment before administering it. (*Id.* § 8.7.) Determining an estimated glomerular filtration rate for a patient is a method for determining renal impairment. The NUMBRINO Label further instructs medical professionals to administer NUMBRINO by soaking a plurality of absorbent articles in NUMBRINO which is an aqueous solution comprising sodium benzoate, citric acid, and about 4% cocaine hydrochloride, by weight; contacting at least one of the plurality of absorbent articles with a mucous membrane of the patient for up to about 20 minutes to reduce sensation in a body region of the patient. (*Id.* §§ 2.3, 11.) The NUMBRINO Label further instructs medical professionals to use NUMBRINO in patients with renal impairment. (*Id.* § 8.7.) Individuals with renal impairment have estimated glomerular filtration rate ranges from about 15 mL/min./1.73 m² to less than about 60 mL/min./1.73 m².

82. Claim 15 claims the method of claim 12, wherein the aqueous solution further comprises at least one coloring additive. Lannett induces infringement of claim 15 because NUMBRINO includes D&C Yellow No. 10 (a coloring additive) and FD&C Green No. 3 (a coloring additive). (*Id.* § 11.)

83. Claim 18 claims the method of claim 12, wherein the medical procedure comprises nasal endoscopy. Lannett induces infringement of claim 18 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.* § 1.) A nasal endoscopy is a type of medical procedure on or through the nasal cavities in adults.

84. Claim 19 claims the method of claim 12, wherein the medical procedure comprises laryngoscopy. Lannett induces infringement of claim 19 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.” (*Id.*) A laryngoscopy is a type of medical procedure on or through the nasal cavities in adults.

85. Claim 20 claims the method of claim 12, wherein the medical procedure is at least one procedure selected from the group consisting of nasopharyngeal laryngoscopy, nasal laryngoscopy, nasal debridement, intraturbinate methylprednisolone acetate injection, turbinate reduction, transnasal esophagoscopy, sinuplasty, nasal cauterization, stroboscopy, nasal stroboscopy, and polypectomy. Lannett induces infringement of claim 20 because the NUMBRINO Label instructs medical professionals to administer NUMBRINO “for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and

surgeries on or through the nasal cavities in adults.” (*Id.*) One or more of the procedures selected from the group consisting of nasopharyngeal laryngoscopy, nasal laryngoscopy, nasal debridement, intraturbinate methylprednisolone acetate injection, turbinate reduction, transnasal esophagoscopy, sinuplasty, nasal cauterization, stroboscopy, nasal stroboscopy, and polypectomy include diagnostic procedures or surgeries on or through the nasal cavities.

86. Lannett, acting without authority, consent, right, or license of the ’760 patent, has induced, and continues to induce medical professionals to administer and use NUMBRINO which directly infringes one or more claims of the ’760 patent resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(b). More specifically, medical professionals directly infringe (literally and/or under the doctrine of equivalents) at least claims 1, 4, 7–12, 15, and 18–20 of the ’760 patent by using NUMBRINO, resulting in conduct that constitutes, at a minimum, patent infringement under 35 U.S.C. § 271(a).

87. On information and belief, Lannett actively and knowingly causes third parties to infringe claims 1, 4, 7–12, 15, and 18–20 of the ’760 patent with the specific intent to cause such infringement. Lannett possessed, and continues to possess, specific intent to induce infringement by providing to the public, at a minimum, the NUMBRINO Label, which provides instructions on how to use NUMBRINO in a manner that infringes directly the ’760 patent.

88. Lannett has actively induced and encouraged, and continues to actively induce and encourage, medical professionals to use NUMBRINO by marketing, promoting and advertising the infringing use of NUMBRINO.

89. Lannett’s foregoing actions constitute active inducement of infringement of the ’760 patent.

90. Upon information and belief, Lannett has acted with full knowledge of the ’760

patent and without a reasonable basis for believing that it would not be liable for active inducement of infringement of the '760 patent.

91. Genus has been damaged as a result of Lannett's infringing conduct.

92. Lannett is thus liable to Genus in an amount that adequately compensates for its infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

93. On information and belief, Lannett has willfully infringed the '760 patent. Genus is entitled to increased damages of three times the damages assessed pursuant to 35 U.S.C. § 284, as well as an award of attorney's fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Genus respectfully requests that this Court enter a Judgment and Order:

- a) Declaring that the Patents-in-Suit are valid and enforceable;
- b) Declaring that Lannett infringes of at least one valid and enforceable claim of the Patents-in-Suit under 35 U.S.C. § 271(b);
- c) Declaring that Lannett's infringement is willful and Genus is entitled to treble damages under 34 U.S.C. § 284;
- d) Awarding Genus damages adequate to compensate for Lannett's infringement, but in no event less than a reasonable royalty;
- e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Genus its attorneys' fees, costs, and expenses, based in part on, but not limited to, Lannett's willful infringement; and
- f) Granting Genus such other and further relief as this Court deems just, proper, and equitable.

JURY DEMAND

Genus demands a trial by jury on all issues which can be heard by a jury.

Dated: June 8, 2020

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